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(73) Proprietor: **Colgate-Palmolive Company**
300 Park Avenue
New York, N.Y. 10022-7499(US)

(72) Inventor: **Mei-King Ng, Shirley**
8 Brian Drive
Bridgewater, NJ(US)
Inventor: **Wieckowski, Susan**
210 Julius Street
Iselin, NJ(US)

(74) Representative: **UEXKÜLL & STOLBERG Patentanwälte**
Beselerstrasse 4
W-2000 Hamburg 52(DE)

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D scription

The present invention relates to the formation of a cosmetic and chemically stable aqueous hydrogen peroxide-containing dental gel having an acid pH of 4.5-6.0, comprising a compatible system of specified amounts of specific dental components.

Until now, it has been difficult to formulate a cosmetic and chemically stable hydrogen peroxide gel with appropriate thickening/gelling agents, humectants, surfactants and flavor for oral application. However, after extensive experimentation on various mixtures of components in the hydrogen-peroxide dental gel product, a compatible system of water, polyoxyethylene-polyoxypropylene block copolymers gelling agent, polyethylene glycol humectant, non-ionic surfactant, sweetening agent and flavor has been discovered. This dental product is in the form of a stable rigid gel having improved chemical and cosmetic stability and improved taste.

It has long been recognized in the art that hydrogen peroxide and other peroxygen-containing agents are effective in curative and/or prophylactic treatments with respect to cleaning, caries-dental plaque, gingivitis, periodontitis, mouth odor, tooth stains, recurrent aphthous ulcers, denture irritations, orthodontic appliance lesions, postextraction and postperiodontal surgery, traumatic oral lesions and mucosal infections, herpetic stomatitis and the like. Peroxide-containing agents in the oral cavity exert a chemomechanical action generating thousands of tiny oxygen bubbles produced by interaction with tissue and salivary enzymes. Peroxide mouthrinses and other oral preparations prevent colonization and multiplication of anaerobic bacteria known to be associated with periodontal disease. Peroxygen-containing gels or pastes are indicated and/or desirable where it is required to selectively treat areas for more than a few seconds, such gels and pastes tending to remain at the site of application for a time sufficient for the peroxide to manifest its maximum effectiveness.

It is also known that most peroxy compounds such as hydrogen peroxide in oral compositions tend to be unstable in storage due to incompatibility with, or interaction with, other common ingredients in the composition, and loose the capacity to release active or nascent oxygen over relatively short periods of time. This adversely affects both the chemical stability of the composition as well as the cosmetic stability of the final product, particularly in the gel product containing hydrogen peroxide.

The prior art has attempted to solve said problems by using a variety of stabilizers for dental compositions in assorted forms such as tablets, chewing gum, mouthwashes, toothpastes or powder containing a hydrogen peroxide, as shown in U.S. Patent No. 4,226,851 wherein is disclosed an aqueous mouthwash containing hydrogen peroxide, flavor, zinc chloride and water soluble Vitamin E which stabilizes the hydrogen peroxide in the mouthwash. U.S. Patent No. 4,302,851 discloses solid oral products (tablets and chewing gum) containing urea hydrogen peroxide in gum bases such as jelutong, rubber latex, vinylite resins, etc., and in methyl, ethyl and sodium carboxymethyl cellulose carriers, free of glycerol, also containing sweeteners such as sodium saccharinate, xylitol, sorbitol, and mannitol and flavors.

U.S. Patent No. 4,476,108 discloses an admixture of a peroxidase, a peroxide and a donor molecule such as phenylethylamine, tryptophan, benzoic acid, salicylic acid, hydroquinone, dihydrophenyl-alanine, vanillan and paraaminobenzoic acid, in a carrier such as water (mouthwash) or in the form of a paste, gel or powder. U.S. Patent No. 4,431,631 discloses an aqueous oral solution containing hydrogen peroxide, glycerin and/or sorbitol humectant, 0.5-3% pluronic-type surfactant, polyoxyethylenated sorbitol monofatty acid ester surfactant, sweetener and flavor.

The prior art also discloses dental compositions containing a hydrogen peroxide and an additional component to effect stabilization, such as ascorbic acid in U.S. Patent No. 3,886,265, wherein is disclosed tablets, lozenges, chewing gum or an aerosol or spray form containing a peroxide such as hydrogen peroxide and an ene-diol compound such as ascorbic acid, effective against bad breath.

U.S. Patent 4,521,403 discloses a method of controlling and treating periodontal diseases by washing the teeth with an aqueous or aqueous alcoholic solution of a hydrogen peroxide and a povidone-iodine complex (complex of iodine with 1-vinyl-2-pyrrolidone polymers). These two ingredients are mixed only prior to use. U.S. Patent No. 4,592,487 discloses an antiplaque dentifrice in the form of a toothpaste or gel containing the two components, a peroxide and povidone-iodone complex, each separately mixed with conventional dentifrice components, and kept separated until admixed and dispensed from a special dual compartment container/mixer/dispenser device.

U.S. Patent No. 4,592,488 discloses an oral composition containing an iodophor or quaternary ammonium compound and a peroxy compound such as hydrogen peroxide in the form of an aqueous or aqueous alcoholic solution prior to combining the two components into an oral mouthwash.

U.S. Patent No. 4,592,489 discloses a two-part container for dispensing an oral mouthwash containing the povidone-iodine complex solution separate from the hydrogen peroxide solution and mixing prior to

dispensing.

Dental compositions containing other oxidizing agents in lieu of the hydrogen peroxide are also disclosed in the prior art.

U.S. Patents 4,522,805 and 4,567,036 disclose a stable toothpaste to aid in controlling periodontal disease, containing an oxidizing agent such as carbamide peroxide (urea peroxide) which dissociates into urea and hydrogen peroxide in the oral cavity, in a paste carrier comprising an anionic detergent, sorbitol and glycerin humectant and a thickening agent such as gum tragacanth, sodium alginate or sodium carboxymethyl cellulose.

U.S. Patent No. 4,405,599 discloses toothpaste containing calcium peroxide and sodium perborate oxidizing agents; dicalcium phosphate, calcium carbonate and magnesium carbonate cleaning agents; sorbitol humectant; cornstarch and cellulose gum thickening agents, and an anionic detergent.

U.S. Patent No. 4,223,003 discloses a toothpaste or toothpowder containing peroxide-containing substances such as magnesium peroxide and conventional dentifrice components. U.S. Patent No. 4,537,765 discloses a toothpaste having a pH of 9.2-10.5 containing a peroxydiphosphate salt, a polyethylene glycol humectant, a thickener such as colloidal silica, carboxyvinyl polymer, cellulose gums, or hectorite; a polishing agent such as silica or hydrated alumina and anionic or nonionic surfactants such as Pluronic® F108.

However, none of the aforesaid patents disclose the preparation of hydrogen peroxide dental gels containing the essential specific components of a polyethylene glycol humectant, a nonionic surfactant, flavor, and a polyethylene polypropylene block copolymer thickening agent in the formation of a stable dental gel.

The prior art also discloses processes of preparing other peroxide gels as shown in U.S. Patent No. 3,657,413 and the article by Assasy et al, "Stability of Hydrogen Peroxide in Certain Pharmaceutical Gels", Cosmetics and Toiletries, 54-56, 91, September 1976. The patent discloses a clear gel comprising urea peroxide, glycerol, a carboxypolymethylene polymer and flavor; prepared by dispersing the polymer into the glycerol with high speed stirring at reduced pressure and then dissolving the urea peroxide and other ingredients in the thickened polymer/glycerol solution yielding a viscous gel. The article discloses methyl cellulose gels for treating surface cuts, bleaching hair and for deodorant purposes containing 0.1% oxine as stabilizer for the hydrogen peroxide; prepared by dispersing the methyl cellulose in water using an electric stirrer and then neutralizing with tri-ethanolamine to yield a gel; or dispersing in hot water until well hydrated, refrigerating until solidified and stirring until a gel is obtained, adding the stabilizer oxine to the gel, followed by the addition of the hydrogen peroxide. Other stabilizers which are not as effective as oxine include hexamine, benzoic acid and urea.

Hydrogen peroxide gels containing polyoxyethylene polyoxypropylene block copolymers as the gelling/thickening agent is disclosed in U.S. Patents No. 3,639,574 and 4,537,778. The former patent discloses a stable hydrogen peroxide gel for use in hair bleaching and treating surface cuts, using polyoxyethylene polyoxypropylene block copolymers as gelling agents in amounts of 22-79% of the total compositions.

This is not a dental gel, does not contain the polyethylene glycol humectant, sodium saccharine sweetener, or flavor which are essential ingredients in the dental gel. The latter patent discloses an aqueous oral preparation which may be in the form of a mouthrinse, a paste or a gel containing hydrogen peroxide, a flavor and 20% of a thickener (for the gel form), 1-20% polyhydric alcohols such as glycerol and sorbitol, 0.1-10% nonionic surfactants such as Tweens® (polysorbate) and/or Pluronics®. The Pluronic® (F127) is the preferred gelling agent (5-50%). There is no mention of polyethylene glycol humectant which is the exclusive effective humectant used in this formulation.

Moreover, the prior art does not disclose a cosmetically and chemically stable aqueous hydrogen peroxide dental gel having a pH of 4.5-6.0 containing as the essential ingredients, a polyoxyethylene polyoxypropylene block copolymer gelling agent, a polyethylene glycol humectant, a nonionic surfactant, sweetener, i.e. sodium saccharin and flavor, in specified proportions.

It has now been found that an aqueous hydrogen peroxide dental gel can be stabilized in the presence of polyethylene glycol, sodium saccharin, nonionic surfactant and flavor when using a polyethylene polypropylene block copolymer (Pluronics)® at a level of 18-25% by weight as the gelling agent. The Pluronic® gelling agents are compatible with the aqueous hydrogen peroxide, whereas the natural gums derived from organic material such as the alginate, methyl cellulose and the like are degraded by the hydrogen peroxide, resulting in unstable gels. Similarly, synthetic organic polymers such as polyvinylpyrrolidone form a stringy gel, which is not the clear, homogeneous rigid gel in accordance with present novel dental gel product. The presence of stabilizers such as sodium stannate, sodium pyrophosphate, oxine EDTA and calcium disodium EDTA have been found to be unnecessary and undesirable, because their

presence provide no advantages to the composition. As a matter of fact their presence tend to adversely affect the chemical stability of the H_2O_2. The combination of polyethylene glycol humectant and the block copolymer gelling agent has been found to yield a more stable rigid gel than a gel prepared with the block copolymer gelling agent in the absence of the polyethylene glycol. The use of nonionic surfactants have been found to have acceptable stability in an aqueous peroxide environment. The anionic surfactants do not have acceptable stability in the presence of hydrogen peroxide.

Accordingly, a primary object of the present invention is to formulate a cosmetically and chemically stable hydrogen peroxide dental gel having a pH of 4.5-6.0 containing a polyethylene polypropylene block copolymer gelling agent in amounts of 18-25% by weight of the composition which is compatible with H_2O_2.

Another object of this invention is to provide a cosmetically stable H_2O_2-polyethylene polypropylene block copolymer gel containing polyethylene glycol humectant which is compatible with the other dental ingredients.

Still another object of this invention is to provide a cosmetically and chemically stable aqueous H_2O_2 dental gel having improved taste, containing a compatible formulation of the block copolymer gelling agent, polyethylene glycol humectant, nonionic surfactant, flavor and sweetening agent, such as sodium saccharine.

Additional objects, advantages and novel features of the invention will be set forth in part in the description which follows, and in part will become apparent to those skilled in the art upon examination of the following or may be learned by practice of the invention. The objects and advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

To achieve the foregoing and other objects in accordance with the present invention, as embodied and broadly described herein, the novel stable aqueous hydrogen peroxide dental gel of this invention comprises 1.5-3.5% by weight H_2O_2 as the sole chemically active agent, 18-25% by weight of a solid flake or powder polyoxyethylene polypropylene block copolymer gelling agent (Pluronic)®, 15-40% by weight of a polyethylene glycol humectant, a nonionic surfactant, sweetener and flavor, said gel having an acid pH of 4.5-6.0. Sodium saccharin is the preferred sweetener. The water content in the gel constitutes preferably 30-60% by weight of the oral composition. Distilled or deionized water is preferred to prevent minimal contamination.

The hydrogen peroxide formulation of present invention contains an effective amount of hydrogen peroxide for oral anti-gingivitis application which is 1.5-3.5% by weight of the composition. Hydrogen peroxide is usually supplied as 30-35% aqueous solutions containing 1.5-3.5% active ingredient. The hydrogen peroxide is stable in the presence of polyethylene glycol, sodium saccharin, nonionic surfactant, flavor, and the Pluronic gelling agent.

An essential ingredient in present H_2O_2 gel dentifrice is a compatible peroxide-stable thickening and gelling agent which is a polyoxyethylene polyoxypropylene block copolymer in an amount of 18-25% by weight of the composition. Amounts less than 18% provide insufficient thickening for the hydrogen peroxide gel dentifrice; and amounts greater than 25% are difficult to formulate. Useable agents include Pluronic® Polyols which are nonionic and may be represented by the formula

$$HO(C_2H_4O)_b(C_3H_6O)_a(C_2H_4O)_bH$$

wherein a is an integer such that the hydrophobic base represented by (C_3H_6O) has a molecular weight of 2250 to 4000, b is an integer such that the hydrophilic portion (moiety) represented by (C_2H_4O) constitutes 70-80% by weight of the copolymer. Pluronic® Polyols of the F (solid flake or powder) type, with a hydrophobe of M.W. of 2750 to 4000 and with from 70 to 80% hydrophilic polyoxyethylene groups form a gel at 18-25% by weight of the H_2O_2/Pluronic® gel formulation. Examples of suitable Pluronic® compounds are Pluronic® F88, F98, F108 and F127. The most preferred gelling agent is Pluronic® F127, which has a molecular weight of 400 and contains 70% of the hydrophilic polyoxyethylene moiety. It is most preferably employed in the gel dentifrice in an amount of about 18-19% by weight.

The completed 12 weeks accelerated temperature aging data of aqueous Pluronic®-H_2O_2 gels with and without stabilizers are acceptable both cosmetically and chemically, except for a formula which contained sodium lauryl sulfate, anionic surfactant. Sodium stannate, sodium pyrophosphate, oxine, phosphoric acid and disodium EDTA are effective in stabilizing aqueous H_2O_2 systems. However, results from the active oxygen data suggest that the system which contains no stabilizers appears to be the best chemically. 90% of H_2O_2 activity was available after 6 weeks of cosmetic aging (accelerated temperature aging). Rheological results indicate that the Pluronic gels are quite stable in terms of yield point and resolidification points. The

gels do not thicken up with time and after 12 weeks at 37.8°C the yield point only decreased by 10% which is within experimental error.

Another essential ingredient in the H_2O_2 gel formulation of present invention is the polyethylene glycol humectant which is compatible with the hydrogen peroxide, the non-ionic surfactant, flavor and the Pluronic® gelling agent.

Polyethylene glycols known by the trademark CARBOWAX® are nonionic polymers of ethylene oxide having the general formula:

$$HOCH_2(CH_2OCH_2)_nCH_2OH$$

wherein n represents the average number of oxyethylene groups. The Carbowax® polyethylene glycols are designated by a number such as 400, 600, etc. which represents the average molecular weight. The average molecular weight of the polyethylene glycols used herein is 200-1000, more preferably 400-600 and most preferably 600. The polyethylene glycols 200, 300, 400 and 600 are clear viscous liquids at room temperature. They are less hygroscopic than glycerin and simple glycols, are water soluble and form a clear aqueous solution. The polyethylene glycols provide a different and better feel and taste to the dental product than the glycerin or sorbitol. It has been found that the polyethylene glycol humectant also aids in making a superior stable rigid Pluronic® H_2O_2 gel to the gel with glycerine. The polyethylene glycol humectant constitutes 15-40% by weight of the H_2O_2 formulation.

Another essential ingredient in the aqueous H_2O_2 gel formulation of this invention is the nonionic surfactant which is compatible with the H_2O_2 and is peroxide-stable. The nonionic surfactant serves as a solubilizing, dispersing, emulsifying and wetting agent and is especially effective in solubilizing the flavor. A particularly useful nonionic surfactant is a water soluble polyoxyethylene monoester of sorbitol with a C_{10} to C_{18} fatty acid, known under the Tween trademark. The Tween® surfactants are mixtures of C_{10}-C_{18} fatty acid esters of sorbitol (and sorbitol anhydrides), consisting predominantly of the monoester, condensed with about 10-30, preferably 20, moles of ethyleneoxide. The fatty acid (aliphatic hydrocarbon-monocarboxylic acid) may be saturated or unsaturated, e.g. lauric, palmitic, stearic, oleic acids. Polysorbate 20 (e.g. Tween® 20) is especially preferred, and is commonly referred to as polyoxyethylene (20) sorbitan monolaurate. The nonionic surfactant constitutes 0.5 to 5.0% by weight and more preferably 0.5 to 3% by weight of the gel composition.

Another essential ingredient or present aqueous H_2O_2 gel dentifrice is an effective flavoring amount of a flavor compatible and stable with the hydrogen peroxide. The flavor ingredient constitutes 0.5-2% by weight. Suitable flavoring constituents are flavoring oils, e.g. oils of spearmint, peppermint, wintergreen, sassafras, clove, sage, eucalyptus, marjoram, cinnamon, and methyl salicylate, an menthol.

A sweetening material is preferably also employed as a complement to the flavoring material. Suitable sweetening agents are water soluble and include sodium saccharin, sodium cyclamate, xylitol, perillartine, D-tryptophan, aspartame, dihydrochalcones and the like, in concentrations of 0.01 to 1.0% by weight. Sodium saccharine is preferred.

The pH of the H_2O_2 gel dentifrice of the invention ranges from 4.5 to 6.0. The pH of the prepared composition is generally adjusted to about 5.0 to 6.0 with an appropriate acid such as phosphoric acid or citric acid, and the pH decreases to approximately 4.5 after 12 weeks accelerated aging. This acidic pH affords greater stability to the gel product of present invention, the lower the pH the greater the stability.

The hydrogen peroxide gel dentifrice of this invention may also Contain conventional additional ingredients such as coloring or whitening agents, or preservatives such as sodium benzoate, in minimal amounts of up to 5% by weight and preferably up to 1%, provided they do not interfere with the chemical and cosmetic (physical) stability properties of the finished product.

It has been found that only by utilizing the specific combination of ingredients of nonionic surfactant, polyethylene glycol humectant, polyoxyethylene polyoxypropylene block copolymer (Pluronics®) gelling agent, sweetening agent and flavor, can a cosmetic and chemically stable aqueous hydrogen peroxide gel dentifrice having improved taste, be formulated.

The rigid stable hydrogen peroxide dental gel of this invention may be prepared by dissolving the hydrogen peroxide, saccharin and the Pluronic® gelling agent in the formula amount of water, preferably deionized water (to prev nt even minimal contamination) heated to a temperature of about 32-32.5°C by mixing in any suitable mixer, such as a Ross mixer, under vacuum for about 30 minutes until a gel is formed. The flavor, nonionic surfactant and polyethylene glycol are added to the gel and mixed under vacuum for about another 15-30 minutes. A rigid, clear, homogeneous stable gel dentifrice product is obtained which may be acidified to a pH of about 5-6 with phosphoric acid or citric acid, if necessary. The final product may be packaged in any suitable container compatible with hydrogen peroxide, such as plastic

or metal tubes; or in a dual compartment container or kit with a bicarbonate dentifrice. This is the preferred method of preparation because it is a faster and more simple method of preparation.

Another method of preparing the hydrogen peroxide dental gel of present invention comprises dissolving the Pluronic® gelling agent in the formula amount of water cooled o about 4-10°C, followed by the addition of the hydrogen peroxide, and the saccharin in the formation of a water phase; separately emulsifying the flavor with the nonionic surfactant in a small amount of water to form an emulsion; adding the humectant and the above emulsion to the Pluronic® water phase and mixing under vacuum until a clear, homogeneous gel is formed.

The final product is a rigid ringing gel which may be described as gels that have a firm jelly-like consistency; that is, when said gel is packed in a jar type container, and the sides of said container are tapped lightly, the gel vibrates but retains its original configuration. The dental gel product of present invention is a dentifrice and not a mouthrinse, and will dissolve in the oral cavity only upon brushing.

In the practice of this invention to promote oral hygiene, the gel dentifrice according to this invention is applied regularly to dental enamel by brushing the teeth for 30-90 seconds at least once daily.

The following examples are further illustrative of the nature of the present invention. The compositions are prepared in the usual manner and all amounts and proportions referred to herein and in the appended claims are by weight unless otherwise indicated.

Example 1

Ingredients	%
Deionized Water	42.10
Pluronic® F127	25.00
Na Saccharin	0.20
H_2O_2 (30% aqueous Solution)(3% A.I.)	10.00
Polyethylene Glycol (mol. wt. 600)	15.00
Deionized Water	5.00
Tween® 20'	1.20
Flavor	1.50
pH - 6.5	
'polyoxyethylene (20) sorbitan monolaurate,	

The formula amount of deionized water is heated to about 32.2°C and mixed together with the saccharin and hydrogen peroxide, and placed in a Ross mixer, the surface is covered completely with the Pluronic® compound and mixed under vacuum at speed 3 for 1/2 hour. The Tween®, flavor and 5% deionized water mixture and the polyethylene glycol are added to the aqueous phase in the Ross mixer and mixed under vacuum at Speed 3 for about 15-25 minutes. A clear and homogeneous rigid gel is obtained having a pH of 6.5 which may be adjusted to a pH of 5-6, with 10% phosphoric acid or citric acid. A stable rigid gel is obtained having excellent storage stability with respect to flavor, color, appearance, taste and peroxy content.

After twelve weeks of accelerated aging, the pH decreases to approximately 4.5. The data show less than 10.0% loss of active oxygen. This formulation has 2.9% active oxygen initially and after aging 9 weeks at 43.3°C has 2.8% active oxygen.

Example 2

Ingredients	%
Deionized Water	48.50
Pluronic® F127	20.00
Na Saccharin	0.20
H_2O_2 (35% Aqueous solution) (3.01% A.I.)	8.60
Polyethylene glycol (mol. wt. 600)	15.00
Deionized Water	5.00
Tween® 20	1.20
Flavor	1.50

The dental hydrogen peroxide gel formulation is prepared by the same procedure outlined in Example 1. The resultant product also exhibits excellent storage stability and is in the form of a stable rigid clear gel.

Example 3

Example 2 is repeated except that polyethylene glycol (400 mol. wt.) is substituted for the polyethylene glycol (600 M.W.). The end product is equally effective aganst gingivitis released bacteria and also possesses excellent chemical and cosmetic stability properties. This product has 2.76% active oxygen initially, and after aging 9 weeks at 43.3 ° C has 2.59% active oxygen.

Example 4

Example 2 is repeated except that the sodium saccharin is omitted and the deionized water content is increased to 48.7%. The omission of the sodium saccharin had no adverse affects on the final hydrogen peroxide dental gel.

Example 5

Example 1 is repeated except that 18% Pluronic® F127 is used instead of 25% and the water content is increased to 49.10%. The resultant product possesses excellent chemical and cosmetic stability similarly to Example 1.

Claims

1. A stable aqueous hydrogen peroxide dental gel comprising 1.5 - 3.5% by weight hydrogen peroxide, 18 - 25% by weight of a solid flake or powder polyoxyethylene polyoxypropylene block copolymer gelling agent, 15 to 40% by weight of a polyethylene glycol humectant, a nonionic surfactant, and a flavor, said gel having an acid pH of 4.5 to 6.0.

2. The dental gel according to Claim 1 including a sweetening material.

3. The dental gel according to Claim 2 wherein the sweetening material is sodium saccharin.

4. The dental gel according to Claim 1, wherein the gelling agent is a solid polyoxyethylene polyoxypropylene copolymer wherein the polyoxypropylene hydrophobic moiety has a molecular weight of 2250 to 4000 and the hydrophilic polyoxyethylene moiety constitutes 70 - 80% of the copolymer.

5. The dental gel according to Claim 4 wherein the gelling agent constitutes 18 - 19% by weight of the composition.

6. The dental gel according to Claim 1, wherein the polyethylene glycol humectant has an average molecular weight of 200 - 1000.

7. The dental gel according to Claim 6, wherein the polyethylene glycol has an average molecular weight of 400 - 600.

8. The dental gel according to Claim 1, wherein the nonionic surfactant constitutes 0.5 - 5% by weight.

9. The dental gel according to Claim 8, wherein the nonionic surfactant is a polyoxyethylene monoester of sorbitol with a C_{10} to C_{18} fatty acid.

10. The dental gel according to Claim 1, wherein the aqueous content constitutes 30 - 60% by weight of deionized water.

11. A dental gel according to Claim 1, wherein the nonionic surfactant constitutes 0.5 - 3% by weight and the flavor content is 0.5 - 2% by weight.

12. A dental gel according to Claim 9, wherein the nonionic surfactant is polyethylene (20) sorbitan monolaurate.

13. A dental gel according to Claim 4, wherein the hydrophobic moiety of the gelling agent has a molecular weight of 4000 and the hydrophilic moiety constitutes 80% by weight of the copolymer.

14. A process of preparing the hydrogen peroxide gel defined in Claim 1 which comprises dissolving the hydrogen peroxide and the block copolymer gelling agent in the formula amount of water heated to 32 °C and mixing under vacuum for 30 minutes to form a gel, adding the polyethylene glycol, flavor and nonionic surfactant to the gel and mixing under vacuum for 15-30 minutes until a rigid, clear, homogeneous gel is obtained.

15. A process of preparing the hydrogen peroxide gel defined in Claim 14, which comprises dissolving the hydrogen peroxide, sodium saccharin and the copolymer gelling agent in the formula amount of deionized water heated to 32 - 32.5 °C and mixing under vacuum for about thirty minutes to form a gel; adding the polyethylene glycol, flavor and nonionic surfactant to the gel and mixing under vacuum for 15 - 30 minutes until a clear, homogeneous, rigid gel is obtained.

Patentansprüche

1. Haltbares, wäßriges Wasserstoffperoxid-Zahngel enthaltend 1,5-3,5 Gew.-% Wasserstoffperoxid, 18-25 Gew.-% eines festen, flockigen oder pulvrigen Polyoxyethylenpolyoxypropylen-Blockcopolymer-Geliermittels, 15-40 Gew.-% eines Polyethylenglykol-Feuchthaltemittels, ein nichtionisches Tensid, und einen Aromastoff, wobei das Gel einen saueren pH von 4,6 bis 6,0 hat.

2. Zahngel nach Anspruch 1 einschließlich eines Süßstoffs.

3. Zahngel nach Anspruch 2, in dem der Süßstoff Natriumsaccharin ist.

4. Zahngel nach Anspruch 1, in dem das Geliermittel ein festes Polyoxyethylenpolyoxypropylen-Copolymer ist, in welchem der hydrophobe Polyoxypropylenanteil ein Molekulargewicht von 2250 bis 4000 hat und der hydrophile Polyoxyethylenteil 70-80 % des Copolymers ausmacht.

5. Zahngel nach Anspruch 4, in dem das Geliermittel 18-19 Gew.-% der Zusammensetzung ausmacht.

6. Zahngel nach Anspruch 1, in dem das Polyethylenglykol-Feuchthaltemittel ein durchschnitliches Molekulargewicht von 200-1000 hat.

7. Zahngel nach Anspruch 6, in dem das Polyethylenglykol ein durchschnittliches Molekulargewicht von 400-600 hat.

8. Zahngel nach Anspruch 1, in dem das nichtionische Tensid 0,5-5 Gew.-% ausmacht.

9. Zahngel nach Anspruch 8, in dem das nichtionische Tensid ein Polyoxyethylenmonoester von Sorbit mit einer C_{10}- bis C_{18}-Fettsäure ist.

10. Zahngel nach Anspruch 1, in dem der Wassergehalt 30-60 Gew.-% entmineralisiertes Wasser beträgt.

11. Zahngel nach Anspruch 1, in dem das nichtionische Tensid 0,5-3 Gew.-% ausmacht und der Gehalt an

Aromastoff 0,5-2 Gew.-% ist.

12. Zahngel nach Anspruch 9, in dem das nichtionische Tensid Polyethylen(20)sorbitanmonolaurat ist.

13. Zahngel nach Anspruch 4, in dem der hydrophobe Teil des Geliermittels ein Molekulargewicht von 4000 besitzt und der hydrophile Anteil 80 Gew.-% des Copolymers ausmacht.

14. Verfahren zum Herstellen des in Anspruch 1 definierten Wasserstoffperoxidgels, **gekennzeichnet** durch Auflösen des Wasserstoffperoxids und des Blockcopolymer-Geliermittels in der Formulierungsmenge an auf 32 °C erwärmtem Wasser und Vermischen während 30 Minuten im Vakuum zur Bildung eines Gels, Hinzufügen des Polyethylenglykols, Aromastoffs und nichtionischen Tensids zu dem Gel und Vermischen unter Vakuum während 15-30 Minuten, bis ein starres, klares homogenes Gel erhalten wird.

15. Verfahren zum Herstellen des in Anspruch 14 definierten Wasserstoffperoxidgels, **gekennzeichnet** durch Auflösen des Wasserstoffperoxids, Natriumsaccharins und des Copolymer-Geliermittels in der Formulierungsmenge an entmineralisiertem Wasser, das auf 32-32,5 °C erhitzt ist, und Vermischen unter Vakuum während etwa 30 Minuten zur Bildung eines Gels; Zugeben des Polyethylenglykols, Aromastoffs und nichtionischen Tensids zu dem Gel und Vermischen unter Vakuum während 15-30 Minuten, bis ein klares, homogenes, starres Gel erhalten wird.

Revendications

1. Gel dentaire aqueux stable contenant du peroxyde d'hydrogène, comprenant 1,5 à 3,5 % en poids de peroxyde d'hydrogène, 18 à 25 % en poids d'un copolymère séquencé polyoxyéthylène-polyoxypropylène solide en poudre ou en paillettes comme agent gélifiant, 15 à 40 % en poids d'un polyéthylène-glycol comme humectant, un agent tensio-actif non ionique et un aromatisant, ledit gel ayant un pH acide de 4,5 à 6,0.

2. Gel dentaire selon la revendication 1, contenant une substance édulcorante.

3. Gel dentaire selon la revendication 2, dans lequel la substance édulcorante est le saccharinate de sodium.

4. Gel dentaire selon la revendication 1, dans lequel l'agent gélifiant est un copolymère polyoxyéthylène-polyoxypropylène solide dont la portion polyoxypropylène hydrophobe a un poids molécualire de 2250 à 4000 et la portion polyoxyéthylène hydrophile constitue 70 à 80 % du copolymère.

5. Gel dentaire selon la revendication 4, dans lequel l'agent gélifiant constitue 18 à 19 % en poids de la composition.

6. Gel dentaire selon la revendication 1, dans lequel le polyéthylène-glycol servant d'humectant a un poids moléculaire moyen de 200 à 1000.

7. Gel dentaire selon la revendication 6, dans lequel le polyéthylène-glycol a un poids moléculaire moyen de 400 à 600.

8. Gel dentaire selon la revendication 1, dans lequel l'agent tensio-actif non ionique constitue 0,5 à 5 % en poids.

9. Gel dentaire selon la revendication 8, dans lequel l'agent tensio-actif non ionique est un monoester polyoxyéthylé de sorbitol avec un acide gras en C_{10} à C_{18}.

10. Gel dentaire selon la revendication 1, dans lequel la teneur en eau est de 30 à 60 % en poids d'eau désionisée.

11. Gel dentaire selon la revendication 1, dans lequel l'agent tensio-actif non ionique constitue 0,5 à 3 % en poids et la teneur en aromatisant est de 05 à 2 % en poids.

12. Gel dentaire selon la revendication 9, dans lequel l'agent tensio-actif non ionique est le monolaurate de polyéthylène(20)-sorbitanne.

13. Gel dentaire selon la revendication 4, dans lequel la portion hydrophobe de l'agent gélifiant a un poids moléculaire de 4000 et la portion hydrophile constitue 80 % en poids du copolymère.

14. Procédé de préparation du gel contenant du peroxyde d'hydrogène défini dans la revendication 1, qui comprend la dissolution du peroxyde d'hydrogène et du copolymère séquencé servant d'agent gélifiant dans la quantité formulée d'eau chauffée à 32 °C et le mélange sous vide pendant 30 minutes pour former un gel, les additions du polyéthylène-glycol, de l'aromatisant et de l'agent tensio-actif non ionique au gel et le mélange sous vide pendant 15 à 30 minutes jusqu'à obtention d'un gel homogène, transparent, rigide.

15. Procédé de préparation du gel contenant du peroxyde d'hydrogène selon la revendication 14, qui comprend la dissolution du peroxyde d'hydrogène, du saccharinate de sodium et du copolymère servant d'agent gélifiant dans la quantité formulée d'eau désionisée chauffée entre 32 et 32,5 °C et le mélange sous vide pendant environ trente minutes pour former un gel ; les additions du polyéthylène-glycol, de l'aromatisant et de l'agent tensio-actif non ionique au gel et le mélange sous vide pendant 15 à 30 minutes jusqu'à obtention d'un gel rigide, homogène, transparent.